



BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2014-0153; FRL-9953-96]

#### Pyriofenone; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of pyriofenone in or on the caneberry subgroup (crop subgroup 13-07A), the bushberry subgroup (crop subgroup 13-07B), the small fruit vine climbing subgroup (crop subgroup 13-07D), the low growing berry subgroup except cranberry (crop subgroup 13-07G) and cucurbit vegetables (crop group 9). ISK Biosciences Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2014-0153, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to

4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: [RDNRNotices@epa.gov](mailto:RDNRNotices@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

*B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at [http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

### *C. How Can I File an Objection or Hearing Request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2014-0153 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2014-0153, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

## II. Summary of Petitioned-For Tolerance

In the **Federal Register** of May 23, 2014 (79 FR 29729) (FRL-9910-29), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 3F8227) by ISK Biosciences Corporation, 7470 Auburn Road, Suite A Concord, OH 44077. The petition requested that 40 CFR part 180 be amended by proposing tolerances for residues of the fungicide, pyriofenone, in or on, the caneberry subgroup (crop subgroup 13-07A) at 0.90 ppm, the bushberry subgroup (crop subgroup 13-07B) at 1.5 ppm, the small fruit vine climbing subgroup (crop subgroup 13-07D) at 1.5 ppm, the low growing berry subgroup except cranberry (crop subgroup 13-07G) at 0.50 ppm, and cucurbit vegetables (crop group 9) at 0.30 ppm. That document referenced a summary of the petition prepared by ISK Biosciences Corporation, the registrant, which is available in the docket, <http://www.regulations.gov>. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

## III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for pyriofenone including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with pyriofenone follows.

*A. Toxicological Profile*

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability, as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The liver (dog, rat, and mouse), kidney (rat and mouse), and cecum (rat) were the primary organs affected by pyriofenone in toxicity studies. Symptoms of liver toxicity observed in the studies were increased weight, dark color, histological abnormalities (liver pigment deposition, microgranuloma, fatty change, necrosis, and focal hepatic congestion), and increases in hepatic enzymes (alkaline phosphatase,  $\gamma$ -glutamyltransferase, and triglycerides) in serum. Indications of kidney toxicity resulting from pyriofenone exposure included increased weight, coarse surface, histological abnormalities (chronic nephropathy, cortical tubular basophilia, cortical scarring, and cortical cysts), increases in ketones in urine, and perigenital staining. Effects of pyriofenone exposure on the cecum included increased weight; and enlargement, distension, and inflammation. Tests were not conducted to determine toxicity through the inhalation route of exposure, because these data were waived. There is no evidence of dermal toxicity at the limit dose.

Exposure to pyriofenone did not result in any developmental effects at the limit dose in rats, but abortions were noted in rabbits at 300 mg/kg/day. The rabbit abortions were associated with decreased maternal body weight gain and food consumption. There were no effects on reproduction observed at the highest dose tested (334 mg/kg/day), and no quantitative or qualitative sensitivity was noted in offspring. There was no evidence of genotoxicity nor an increase in the incidence of tumors. Based on the results of the immunotoxicity study and other studies in the toxicity database, there was no evidence that pyriofenone directly targets the immune system.

Specific information on the studies received and the nature of the adverse effects caused by pyriofenone as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in the documents “Pyriofenone. Human Health Risk Assessment for the Section 3 Registration on: Cucurbit Vegetable (crop group 9) and berry and small fruit, crop group 13-07 (except large shrub/tree berry subgroup 13-07C)” and “Pyriofenone. Revision to Human Health Risk Assessment for the Section 3 Registration on: Cucurbit Vegetable (Crop Group 9) and Berry and Small Fruit, Crop Group 13-07, (Except Large Shrub/Tree Berry Subgroup 13-07C)” in docket ID number EPA-HQ-OPP-2014-0153.

#### *B. Toxicological Points of Departure/Levels of Concern*

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose

at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>. A summary of the toxicological endpoints for pyriofenone used for human risk assessment is shown in Table 1 of this unit.

Table 1.--Summary of Toxicological Doses and Endpoints for pyriofenone for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (All populations)	An endpoint of concern attributable to a single dose was not identified. An acute RfD was not established.		
Chronic dietary (All populations)	NOAEL= 9.1 mg/kg/day UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	Chronic RfD = cPAD = 0.091 mg/kg/day	Carcinogenicity in rat LOAEL = 46.5 mg/kg/day based on chronic nephropathy in females
Incidental oral short-term (1 to 30 days)	NOAEL= 61 mg/kg/day UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	LOC for MOE = 100	Subchronic oral toxicity in rat LOAEL = 150 mg/kg/day based on increased cecum weight in males
Dermal Short-and Intermediate-Term (1-30 days; 1-6 months)	No quantitative dermal assessment needed. No dermal toxicity at limit dose. No increased quantitative or qualitative susceptibility noted in fetus or offspring. Developmental effect (abortions) in rats at 100 mg/kg/day. DAF = 6%. Adjusted value exceeds limit dose. No neurotoxicity observed in ACN and SCN at the limit dose.		
Inhalation short-term and intermediate-	NOAEL= 61 mg/kg/day (inhalation absorption)	LOC for MOE = 100	Subchronic oral toxicity in rat

term (1 to 30 days; 1-6 months)	rate = 100%) UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x		LOAEL = 150 mg/kg/day based on increased cecum weight in males
Cancer (Oral, dermal, inhalation)	Not likely to be carcinogenic to humans		

ACN = Acute Neurotoxicity Battery. DAF = Dermal Absorption Factor. FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. SCN = Subchronic Neurotoxicity Battery. UF = uncertainty factor. UF<sub>A</sub> = extrapolation from animal to human (interspecies). UF<sub>H</sub> = potential variation in sensitivity among members of the human population (intraspecies).

### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to pyriofenone, EPA considered exposure under the petitioned-for tolerances as well as all existing pyriofenone tolerances in 40 CFR 180.660. EPA assessed dietary exposures from pyriofenone in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicological studies for pyriofenone; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA assumed pyriofenone residues are present in all commodities at tolerance levels and that 100% of primary crops are treated. All populations were evaluated for chronic dietary exposure and risk from food and drinking water. No risks of concern were identified in the chronic dietary exposure analysis.



iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that pyriofenone does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information*. Tolerance level residues and 100% crop treated were assumed for all food commodities for pyriofenone.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for pyriofenone in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of pyriofenone. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the Tier 1 Cranberry Model for surface water and Pesticide Root Zone Model Ground Water (PRZM GW) for ground water, the estimated drinking water concentrations (EDWCs) of pyriofenone for acute exposures are estimated to be 20.9 parts per billion (ppb) for surface water and 4.3 ppb for ground water. The chronic exposures for non-cancer assessments are estimated to be 2.7 ppb for surface water and 3.9 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. Because no acute dietary endpoint was identified, no acute dietary assessment was conducted. For the chronic dietary risk assessment, the water concentration of value 3.9 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure*. The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Pyriofenone is not registered

for any specific use patterns that would result in residential exposure. Therefore a residential exposure assessment is not required.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found pyriofenone to share a common mechanism of toxicity with any other substances, and pyriofenone does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that pyriofenone does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

#### *D. Safety Factor for Infants and Children*

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* Exposure to pyriofenone did not result in any developmental effects at the limit dose in rats, but abortions were noted in rabbits at 300 mg/kg/day. EPA is regulating pyriofenone at doses that are protective of this effect. The abortions were associated with decreased maternal body weight gain and food consumption. There were no reproductive effects observed in rats at the highest tested dose (334 mg/kg/day), nor was any quantitative or qualitative sensitivity noted in offspring.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

- i. The toxicity database for pyriofenone is complete.
- ii. There is no indication that pyriofenone is a neurotoxic chemical, and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.
- iii. There is no evidence that pyriofenone results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.
- iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% crop treated and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to pyriofenone in drinking water. These assessments will not underestimate the exposure and risks posed by pyriofenone.

#### *E. Aggregate Risks and Determination of Safety*

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the

estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected.

Therefore, pyriofenone is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to pyriofenone from food and water will utilize 7.2% of the cPAD for children 1 to 2 years old the population group receiving the greatest exposure. There are no residential uses for pyriofenone; therefore, the chronic aggregate risk is limited to the chronic dietary risk and is not of concern

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). There are no residential uses for pyriofenone; therefore, short-term aggregate risks are addressed by the chronic aggregate risk estimates and are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). There are no residential uses for pyriofenone; therefore, intermediate-term aggregate risks are addressed by the chronic aggregate risk estimates and are not of concern.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, pyriofenone is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to pyriofenone residues.

#### **IV. Other Considerations**

##### *A. Analytical Enforcement Methodology*

The petitioner submitted a liquid chromatography method with tandem mass-spectrometry detection (LC-MS/MS) analytical method, ISK Method 0341/074208, for analysis of residues of pyriofenone in/on plant commodities. This method was independently validated to a limit of quantitation of 0.01 ppm in grapes, wheat grain, and wheat straw. To support the new registration actions for pyriofenone, a radiovalidation study was submitted to determine the extraction efficiency of the pyriofenone enforcement method. Radiovalidation testing of Analytical Method ISK 0341/074208 demonstrated an extraction efficiency of approximately 50-60% for pyriofenone residues present in plant samples aged 5½ years.

Adequate enforcement methodology (liquid chromatography method with tandem mass spectrometric detection (LC-MS/MS)) is available to enforce the tolerance expression.

##### *B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL;

however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established MRLs for pyriofenone.

*C. Response to Comments*

One comment was received from a private citizen objecting to establishment of tolerances. The commenter feels that establishment of these tolerances would add to the pesticide body load that is already carried by the human population. In addition, the commenter also indicates that the pesticide body load will increase the exposure to carcinogens and increase the prevalence of cancer.

*Agency response:* The Agency understands the commenter's concerns and recognizes that some individuals believe that pesticides should be banned completely. However, under the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) EPA is authorized to establish pesticide tolerances or exemptions where persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute.

When new or amended tolerances are requested for the presence of the residues of a pesticide and its toxicologically significant metabolite(s) in food or feed, the Agency, as is required by Section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA), estimates the risk of the potential exposure to these residues by performing an aggregate risk assessment. Such a risk assessment integrates the individual assessments that are conducted for food, drinking water, and residential exposures, and also assesses cancer risk. Additionally, the Agency, as is further required by Section 408 of the FFDCA, considers available information concerning what are termed the cumulative toxicological effects of the residues of that pesticide and of other substances having a common mechanism of toxicity with it. For pyriofenone, the Agency has

concluded after this assessment that the pesticide is not carcinogenic, and that there is a reasonable certainty that no harm will result from exposure to residues of this pesticide.

## **V. Conclusion**

Therefore, tolerances are established for residues of pyriofenone, in or on, the caneberry subgroup (crop subgroup 13-07A) at 0.90 ppm, the bushberry subgroup (crop subgroup 13-07B) at 1.5 ppm, the small fruit vine climbing subgroup (crop subgroup 13-07D) at 1.5 ppm, the low growing berry subgroup except cranberry (crop subgroup 13-07G) at 0.50 ppm, and cucurbit vegetables (crop group 9) at 0.30 ppm. Also, the Agency is removing two individual tolerances from the table at 40 CFR §180.660(a) that were not identified in the petition to eliminate redundancies upon the establishment of the recommended crop group and subgroup tolerances: grape at 0.3 ppm, grape, raisin at 0.5 ppm.

## **VI. Statutory and Executive Order Reviews**

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

## **VII. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).





**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 20, 2017.

Richard P. Keigwin, Jr.,  
*Acting Director, Office of Pesticide Program.*

Therefore, 40 CFR part 180 is amended as follows:

**PART 180--[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. In § 180.660, revise the table in paragraph (a) to read as follows:

**§ 180.660 Pyriofenone; tolerance for residues.**

(a) \* \* \*

Commodity	Parts per million
Berry, low growing, subgroup 13-07G (except cranberry)	0.50
Bushberry subgroup 13-07B	1.5
Caneberry subgroup 13-07A	0.90
Fruit, small vine climbing subgroup 13-07D	1.5
Vegetables, cucurbit, crop group 9	0.30

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